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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,463	02/22/2002	Christopher Paul Leamon	ISIS-5023	3043

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WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	**PAPER NUMBER**
1632	10

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,463	LEAMON	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this c mmunication appears n the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

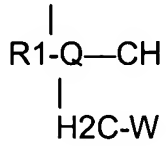
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

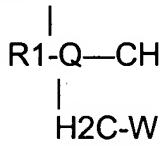
Restriction to one of the following inventions is required under 35 U.S.C. 121:

Invention 1, claim 9-22, 32-46, 54-75 drawn to the a lipid compound having the formula I, wherein X is selected from R1-Q-CH



And
R2-Q, wherein Q is defined in the claim, R2 is the same as R1 (as defined in claim 9);
and wherein Y is defined as set forth in claim 9, with the proviso that Y is not an amino acid residue or a peptide.

Invention 2, claim 9-12, 15-17, 23-31, 54-75, drawn to the a lipid compound having the formula I, wherein X is selected from R1-Q-CH



and
R2-Q, wherein Q is defined in the claim, wherein R2 is the same as R1 (as defined in claim 9);
and wherein Y is an amino acid residue or a peptide.

Invention, 3, claims 5, 6, 9, 12-22, 32-46, 54-75, drawn to the a lipid compound having the formula I, wherein X is selected from R2-Q, wherein R2 is a steroid group, wherein Q is defined in the claim,
and wherein Y is defined as set forth in claim 9, with the proviso that Y is not an amino acid residue or a peptide.

Invention 4, claims 5, 6, 9, 12, 15-17, 23-46, 54-75,drawn to the a lipid compound having the formula I, wherein X is selected from R2-Q, wherein R2 is a steroid group, wherein Q is defined in the claim,
and wherein Y is defined as an amino acid residue or a peptide.

Claims 1-4, 7, 8 are identified as linking claims for inventions 1-4.

Should applicant elects any of inventions 1-4, a further group restriction is required for the following compounds as claimed in claims 47-53, wherein the further elected invention must correspond to the elected invention 1, 2, 3, or 4.

Inventions 1-4/I, claim 47, 48, drawn to a lipid compound as set forth in claims 47 and/or 48, classifiable in class 424, subclass 450.

Invention 1-4/II, claim 49 and 50, drawn to a lipid compound as set forth in claim 49 and/or 50, classifiable in class 424, subclass 450.

Invention 1-4/III, claim 51, drawn to a lipid compound as set forth in claim 51, classifiable in class 424, subclass 450.

Invention 1-4/IV, claim 52, drawn to a lipid compound as set forth in claim 52, classifiable in class 424, subclass 450.

Invention 1-4/V, claim 53, drawn to a lipid compound as set forth in claim 53, classifiable in class 424, subclass 450.

Claims 1 and 9 are identified as linking claims for inventions 1-5.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn

and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 are distinct because R1 and/or Y are distinct structurally, thereby generating a distinct lipid compound, wherein a search and examination of one does not necessarily overlap with another one. Inventions 1-4/1-1-4/V are distinct because each of the inventions is directed to a distinct lipid compound having a distinct structure and/or formula.

Should invention 1-4 be elected, a further species restriction is also required as follows:

Claims 1, 3, 4 are generic to a plurality of disclosed patentably distinct species comprising:

- Oleyl; Linoleyl; Linolenyl, stearyl, eleostearyl, lauryl, and palmityl.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should invention 1, 2, 3, or 4 be elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species of the formula (I) as embraced by the elected invention, even though this requirement is traversed. More specifically, applicant is required to elect a specific combination of X, Y, and Z wherein X, Y, and Z must be defined as a specific named species as listed in the claim.

Should the species of X containing W be elected, applicant is further required to elect a single specific species of W as listed in the claim.

Should the species of W containing R3 be elected, applicant is further required to elect a single specific species of R3 as listed in the claim.

Should a specific species of R1 be elected that corresponds to the elected claimed invention, claim 10 is generic to a plurality of disclosed patentably distinct species comprising: lauryl, myristyl, palmityl, elaidyl, Oleyl, stearyl,, linoleyl, linolenyl, eleostearyl, and phytanyl.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 10 that correspond to the already elected species of the formula (I), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 10 that correspond to the already elected species of the formula (I), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should the peptide group for Y be elected in the lipid compound according the formula (I) of claim 9, which corresponds to the elected claimed invention, claim 23 is generic to a plurality of disclosed patentably distinct species of peptide groups (II)-(V),

wherein each of the cited groups further contain distinct members of species of R3, R4, R5, R6, m, n, o, p, and t.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 23 that correspond to the already elected species of the formula (I), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should the peptide group be elected for Z in the lipid compound according the formula (I) of claim 9, that corresponds to the elected claimed invention, claim 39 is generic to a plurality of disclosed patentably distinct species of peptide groups (IV)-(VIII), wherein each of the cited groups further contain distinct members of species of R3, R4, R5, R6, m, q, r, and t.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species cited in claim 23 that correspond to the already elected species of the formula (I), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because each of the claimed species are structurally distinct for the reasons given above, it would be unduly burdensome for the examiner to search all of the species of the claimed inventions, and thus, restriction for examination purposes as indicated is proper, particularly since it would be unduly burdensome for the examiner to search and/or consider patentability of all of the claims as presently pending.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER